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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,119	09/22/2000	William B. Solomon	011.00250	9568
35876	7590	01/26/2004		
ROGALSKY & WEYAND, LLP P.O. BOX 44 LIVONIA, NY 14487			EXAMINER MARVICH, MARIA	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/668,119	Applicant(s) SOLOMON ET AL.	
	Examiner Maria B Marvich, PhD	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 8 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25 September 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-7, 13-17 and 23.

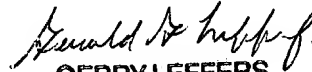
Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE: The amendment does correct the claim listing such that it meets the revised amendment format. Moreover, the claims, if amended as proposed would not avoid the rejection under 35 U.S.C. 101 set forth in the last office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

Continuation of 10. Other: Applicants traverse the claim rejections on pages 7-9 of the amendment filed 12/31/03. Applicants argue that the specification discloses a credible asserted utility for the recited protein and corresponding nucleotide sequence. The disclosure teaches that the protein(s) have transcriptional activation activity (page 15, line 17-18) which is sufficient to satisfy the utility requirement. Further evidence for the utility of TIG-1 as a transcriptional regulator is said to be found on page 29, line 25-30 and page 41, line 29 through page 43 line 14. These sections teach that TIG-1 "may have transcriptional regulatory activity when tethered to DNA" in K562 cells as a Gal4-TIG-1 fusion is associated with TPA induction of CAT activity. That TIG-1 and co-activator complex (ARC) share structural similarity confirms the role of TIG-1 as a transcriptional regulator. Given the real world use of transcriptional regulators and the evidence that TIG-1 functions as a transcriptional activating factor, applicants argue that they have provided a substantial and specific utility.

Applicant's arguments filed 12/31/03 have been fully considered but they are not persuasive. Applicants have cloned TIG-1 from an EST library from TPA-induced K562 cells. Applicants have hypothesized that TIG-1 can behave as a transcriptional activator due to the effect of GAL4-TIG-1 on CAT reporter expression in K562 cells. While this protein has no DNA binding domain, it was further hypothesized that it may function as a transcriptional regulatory protein. Applicants argue that as TIG-1 is therefore a transcriptional regulator, it has a specific and substantial utility. While applicants argue that they must provide only one credible asserted utility in order to meet the criteria for 35 U.S.C. § 101, that transcriptional regulators have substantial and specific functions does not provide a specific benefit of TIG-1 in its currently available form. Applicants have not provided a substantial and specific utility for the claimed polypeptide and nucleotide sequence of TIG-1, and therefore the recited claims lack the substantial utility required by 35 U.S.C. § 101.


GERRY LEFFERS
PRIMARY EXAMINER